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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,478

10/02/2006

Andrew D. Hamilton

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EXAMINER

KATAKAM, SUDHAKAR

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

10/16/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,478	<b>Applicant(s)</b> HAMILTON ET AL.	
	<b>Examiner</b> SUDHAKAR KATAKAM	<b>Art Unit</b> 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4,7,8,13,15,18,20,22 and 35-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,13,15,18,20,22 and 35-45 and 47 is/are rejected.
- 7) ☒ Claim(s) 46 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the application***

1. Receipt of Applicant's request for continued examination filed on 31<sup>st</sup> July 2009 is acknowledged.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31<sup>st</sup> July 2009 has been entered.

2. In view of applicants' amendments and remarks the previous rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of different interpretation of the previously applied reference, newly found prior art and provide an explanation of the rejection.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim subject matter which applicant regards as the invention.

The claim depends on the claim 45, however, it is unclear whether applicants intend to depend on the pharmaceutical composition or a compound. If it is a type in the claim language, then it should be corrected.

***Claim Rejections – 35 USC 102***

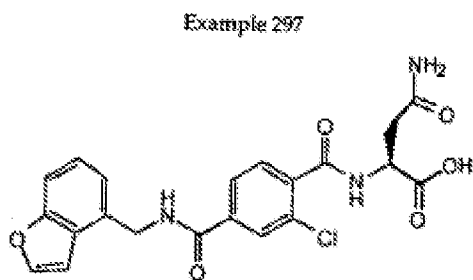
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 7, 8, 13, 18, 20, 35, 39, 40, 41, 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by **Burdick** (WO 99/49856).

**Burdick** discloses the following compound:



[page 141].

The above compound anticipates claims 1, 7 and 8 with the following conditions from the claim language:

R' is substituted C<sub>1</sub> alkyl group;

R<sup>4</sup> is H;

X is H;

X<sup>2</sup> and X<sup>3</sup> are H;

Art Unit: 1621

$X^4$  is Cl;

$R^{1a}$  is H;

$R^{1b}$  is substituted  $C_1$  alkyl group.

The above compound (#297) anticipates claims 1 and 13 with the following conditions from the claim language:

$R'$  is substituted  $C_1$  alkyl group;

$R^4$  is H;

X is Cl;

$X^2$ ,  $X^3$  and  $X^4$  are H;

$R^{1a}$  is H;

$R^{1b}$  is substituted  $C_1$  alkyl group.

The above compound (#297) also anticipates claims 1 and 18 with the following conditions from the claim language:

$R^2$  is substituted alkyl amide;

$R^i$  is H;

j is 0;

$R^4$  is H;

X is Cl;

$X^2$ ,  $X^3$  and  $X^4$  are H;

$R^{1a}$  is H;

$R^{1b}$  is substituted  $C_1$  alkyl group.

The above compound (#297) also anticipates claims 1 and 20 with the following conditions from the claim language:

R' is substituted alkyl group;

R<sup>4</sup> is H;

X<sup>2</sup> is Cl;

X, X<sup>3</sup> and X<sup>4</sup> are H;

R<sup>1a</sup> is H;

n is 0;

R<sup>f</sup> is substituted monoalkylamide;

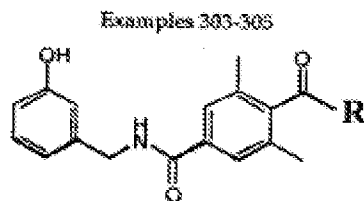
R<sup>g</sup> is H.

**Burdick** also discloses that these compounds can be used in pharmaceutical compositions with a pharmaceutical additive (page 10, lines 8-14; page 61, lines 4-6, 26-34).

Therefore these claims are fully met.

7. Claims 1-4, 36, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by **Burdick** (WO 99/49856).

**Burdick** discloses the following compound:



Examples 303-305 were synthesized by Method 569.

Example #	R group
303	L- Asn
304	L- diaminopropionic acid (allo)
305	L- lys

[page 142].

The above compound (#305) anticipates claims 1-4 with the following conditions from the claim language:

R' is Lysine;

R<sup>4</sup> is H (from -NH- of lysine);

X is methyl group;

X<sup>2</sup> and X<sup>3</sup> are H;

X<sup>4</sup> is methyl group;

R<sup>1a</sup> is H;

R<sup>1b</sup> is substituted C<sub>1</sub> alkyl group.

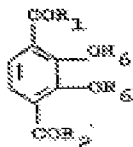
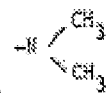
**Burdick** also discloses that these compounds can be used in pharmaceutical compositions with a pharmaceutical additive (page 10, lines 8-14; page 61, lines 4-6, 26-34).

Therefore these claims are fully met.

8. Claims 1, 15 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by **FR 8.298 M** (applicants' IDS 5/18/07).

**FR 8.298 M** discloses the following compound:

Art Unit: 1621

(see page 1, full translation pending), where  $R_1$  and  $R_2$  areand  $R_6$ 

is methyl group [see Table in page 3].

Compound 7 [see Table in page 3] anticipates applicants claims 1 and 15 with the following conditions from the claim language:

$X$  is  $-OR$ , where  $R$  is an unsubstituted  $C_1$  alkyl group;

$X^2$  is  $-OR^e$ , where  $R^e$  is an unsubstituted  $C_1$  alkyl group;

$X^3$  and  $X^4$  are  $H$ ;

$R^4$  is an unsubstituted  $C_1$  alkyl group;

$R'$  is an unsubstituted  $C_1$  alkyl group;

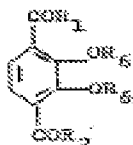
$R^{1a}$  and  $R^{1b}$  are an unsubstituted  $C_1$  alkyl group;

**FR 8.298 M** also discloses pharmaceutical composition or medicament of the above compound [see title and page 1, lines 1-10, translation pending].

Therefore these claims are fully met.

9. Claims 1, 22 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by **FR 8.298 M** (applicants' IDS 5/18/07).

**FR 8.298 M** discloses the following compound:

(see page 1), where  $R_1$  and  $R_2$  are  $-NH-CH_3$  and  $R_6$  is methyl group [see

compound 1 in the Table in page 3].



The above compound anticipates applicants claims 1 and 22 with the following conditions from the claim language:

X is -OR, where R is an unsubstituted C<sub>1</sub> alkyl group, which is a hydrogen bond acceptor group;

X<sup>2</sup> is -OR<sup>e</sup>, where R<sup>e</sup> is an unsubstituted C<sub>1</sub> alkyl group;

X<sup>3</sup> and X<sup>4</sup> are H;

R<sup>4</sup> is H;

R' is an unsubstituted C<sub>1</sub> alkyl group;

R<sup>1a</sup> and R<sup>1b</sup> are an unsubstituted C<sub>1</sub> alkyl group.

**FR 8.298 M** also disclose pharmaceutical composition or medicament of the above compound [see title and page 1, lines 1-10, translation pending].

Therefore these claims are fully met.

#### ***Allowable Subject Matter***

10. Claim 46 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the closest prior art (**Burdick** (WO 99/49856) and **FR 8.298 M**) fails to disclose or teach applicants compound as recited in the claim 46.

#### ***Response to Arguments***

11. Applicant's arguments filed on 31<sup>st</sup> July 2009 have been fully considered but they are not persuasive.

Art Unit: 1621

Applicants' arguments are moot in view of above new grounds of rejection.

***Conclusion***

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/  
Examiner, Art Unit 1621